

EC-2000-007
IU-D-070

BEFORE THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

Establishment of Electronic Reporting;
Electronic Records
Docket No. EC-2000-007

66 Federal Register 46162
August 31, 2001

The Environmental Protection Agency's Cross-Media Electronic Reporting and Record-Keeping Rule (CROMERRR) published in the Federal Register on August 31, 2001, which allows electronic reporting and electronic record-keeping for 40 CFR regulated entities. The direction of CROMERRR is critical to Bayer Corporation, other agrochemical industries, as well as other 40 CFR regulated entities. The following are comments, questions, and concerns with the proposed rule.

- I. Page 46163, *I. Overview, B. What Will the Proposed Regulations Do?* We interpret this section to state electronic (dossier) submissions [when submitted via CD, tape, or diskette] would be excluded from consideration under this proposed rule as stated. Since the submitter is still obligated to submit paper, this would imply that this rule would not carry jurisdiction over electronic (dossier) submissions. Is this a correct interpretation?
- II. Page 46181, *2. The CDX Registration Process*, EPA's proposed registration process is an overkill and an unnecessary invasion of personal privacy. Since these reporting requirements are company based, the types of certifying information should be company's licence and credit card number. The FDA alternative is more simple and still carries the same weight of enforcement too.
- III. Pages 46190 - 46191, *3.30 Subpart C - Electronic Recordkeeping under EPA Programs*
We believe this section either needs to be removed from this rule or greatly modified to take in consideration record retention requirements for 40 CFR regulated entities. Since raw data for FIFRA regulated studies are required to be retained for the lifetime of the registration this may last for many years running into decades.
 - a. One alternative would be to adopt OECD's GLP definition of "raw data" for each computerized system to include computer or instrument printouts. This allows flexibility in the definition and retention of raw data.
 - b. Another reason more flexibility with the retention requirements such as adopting the OECD GLP definition of "raw data" is, many agricultural chemical companies like Bayer Corporation contract studies to outside laboratories. These outside laboratories may or may not use the same equipment, software, etc. as our Bayer Laboratories. We always archive all the original raw data as a security against the contract laboratory going out of business. Without options for retaining records/data in the archive on a different 'media'

than that used to collect the data, we would not be able to comply with the Rule without purchasing and maintaining hardware/software used by every contract laboratory that performs work for us, or limiting our contracting of studies to laboratories which use the same exact hardware and software as us, which is not practical or cost effective.

- c. Another factor to consider is the costs involved in retrofitting or purchasing new systems were grossly underestimated. And in addition, migration of electronic records runs the risk of data corruption or data loss which may need to be performed several times during the lifetime of the FIFRA registration.

We appreciate your consideration of these questions and comments.



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Subject: Comments for docket number EC-2000-007, CROMERRR Rule

Dear Sir/Madame,

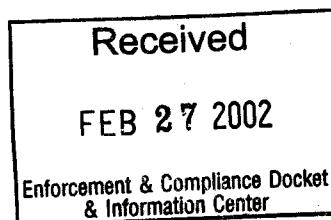
Attached, please find written comments for The Environmental Protection Agency's Cross-Media Electronic Reporting and Record-Keeping Rule (CROMERRR) published in the Federal Register on August 31, 2001, which allows electronic reporting and electronic record-keeping for 40 CFR regulated entities [docket number EC-2000-007]. These comments are in WordPerfect 8. If you have any problems with the file please contact me. Thank you.

Sincerely,

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CROMERRR Comments.wpr